IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE FLONASE ANTITRUST LITIGATION	:	
	:	CIVIL ACTION
THIS DOCUMENT RELATES TO:	:	
	:	NO. 08-3149 (Direct)
ALL ACTIONS	:	NO. 08-3301 (Indirect)
	:	
	:	

ROXANE LABORATORIES, INC., Plaintiff,	:	
	:	CIVIL ACTION
v.	:	
	:	NO. 09-1638
SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Defendant.	:	

June _2__, 2011 **Anita B. Brody, J.**

MEMORANDUM

Flonase is a steroid nasal spray containing the active pharmaceutical ingredient fluticasone propionate ("FP") produced by Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline PLC ("GSK").[1] Until recently, Flonase was one of the nation's top-selling drugs. Three different suits have been filed against GSK, alleging various antitrust violations stemming from GSK's conduct delaying the entry of generic FP nasal sprays into the market. The three suits are brought by: (1) direct purchasers of Flonase in American Sales Co.,

[1] Flonase consists of both the drug, including the aqueous suspension of FP, as well as the metered, atomized spray device that delivers the drug to the active site.

Inc. v. SmithKline Beecham Corp., No. 08-cv-3149 (E.D. Pa. filed July 3, 2008); (2) indirect purchasers of Flonase in IBEW-NECA Local 505 Health & Welfare Plan v. SmithKline Beecham Corp., No. 08-cv-3301 (E.D. Pa. filed July 14, 2008); and (3) Roxane Laboratories, Inc., a manufacturer of a generic FP nasal spray and competitor of GSK in Roxane Laboratories, Inc. v. SmithKline Beecham Corp., No. 09-cv-1638 (E.D. Pa. filed April 17, 2009). GSK has now moved for summary judgment under Fed. R. Civ. P. 56 in all three suits, arguing that its conduct is protected from antitrust liability under the First Amendment and the Noerr-Pennington doctrine. (No. 08-3149 (Direct), ECF No. 151; No. 08-3301 (Indirect), ECF No. 190; No. 09-1638 (Roxane), ECF No. 98). For the following reasons I will **DENY** this Motion.[2]

I. BACKGROUND[3]

A. The Hatch-Waxman Act

Under the Federal Food, Drug, and Cosmetic Act, a company intending to market a drug in the United States must file a "New Drug Application" ("NDA") with the United States Food and Drug Administration ("FDA"). Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1994) (codified at 21 U.S.C. § 301 et seq.). An NDA is a detailed technical document that includes clinical data demonstrating the safety and effectiveness of the new drug.

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[2] GSK has filed additional Motions for Summary Judgment that will not be addressed here: (1) on causation grounds (No. 08-3149 (Direct), ECF No. 150; No. 08-3301 (Indirect), ECF No. 272; No 09-1638 (Roxane), ECF No. 97); and (2) in the Indirect Purchaser action (No. 08-3301 (Indirect), ECF No. 180). This Opinion deals only with GSK's Motion for Summary Judgment on Noerr-Pennington grounds.

[3] For purposes of summary judgment, "the nonmoving party's evidence is to be believed, and all justifiable inferences are to be drawn in [that party's] favor." Hunt v. Cromartie, 526 U.S. 541, 552 (1999) (internal quotation marks omitted). Where facts are disputed, the Plaintiffs' account of the facts will be taken as true for the purposes of this Motion.

The FDA approves the NDA if it meets certain standards. Initially, manufacturers of "generic" drugs were required to file NDAs before they could enter the market.[4] This forced generic drug manufacturers to spend significant amounts of time and money conducting clinical tests.

In 1984, Congress created an expedited approval process for generic drugs by enacting the Hatch-Waxman Act ("Hatch-Waxman"). Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in various sections of titles 15, 21, 35, and 42 of the U.S. Code), as amended by Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, subtits. A-B, 117 Stat. 2066, 2448-64 (codified at 21 U.S.C. § 355). Under Hatch-Waxman, generic manufacturers need only file an Abbreviated New Drug Application ("ANDA") that includes: (1) a demonstration of a certain level of bioequivalence ("BE")[5] to an approved drug, and (2) a Chemistry and Manufacturing Controls ("CMC") section that describes the active and inactive pharmaceutical ingredients used, as well as the quality controls in place to ensure that the product meets certain quality and consistency standards. See 21 U.S.C. § 355(j); 21 C.F.R. § 314.94.

[4] A "generic" drug generally contains the same active ingredients as an approved brand name drug, and is sold after the brand name drug's period of market exclusivity expires. Because generic drug manufacturers do not incur the vast research, development, and marketing costs associated with the creation and promotion of new drugs, generic drug manufacturers are generally able to sell their products at lower prices than their brand name competitors.

[5] Bioavailability ("BA") and bioequivalence ("BE") are related measures. BA measures the rate and extent to which an active ingredient is absorbed and becomes available at the site of action. 21 C.F.R. § 320.1. BE compares the BA of two products. Id.

B. The FDA Guidance Process

Under Hatch-Waxman, the FDA holds a broad degree of discretion in approving ANDAs. In order to keep pharmaceutical manufacturers informed of the FDA's positions on topics related to ANDA approval, the FDA occasionally issues public "guidances." These guidances identify standards and policies that manufacturers can use to develop their products. The FDA issues guidances in accordance with its "good guidance practices." 21 C.F.R. § 10.115. According to those practices, the FDA must solicit public comments on a draft guidance by publishing a notice in the Federal Register. Id. After receiving comments, the FDA can either: (1) issue an updated draft guidance, soliciting further comments; or (2) issue a final guidance. Id.

The FDA is not required to issue guidances. When it chooses to do so, the guidance represents the FDA's view on a given subject, and FDA employees generally may not deviate from a final guidance without "appropriate justification and supervisory concurrence." Id. § 10.115(d)(3). Even a final guidance, however, does not "create or confer any rights for or on any person and does not operate to bind FDA or the public." Def.'s Ex. 10 at 2 (Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action).

C. The Citizen Petition Process

In order to facilitate the drug approval process, the FDA permits private entities to provide comments and opinions on draft guidances by filing "citizen petitions." 21 C.F.R. § 10.30. A petition can request that the FDA "issue, amend, or revoke a regulation or order or take or refrain from taking any other form of administrative action." Id. A citizen petition must describe the FDA action the petitioner requests and must include a certification by the petitioner

that the petition "includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the [petition]." Id. Until 2007, the FDA refrained from approving any ANDA while a citizen petition relating to the ANDA was pending.[6] See Meltzer Decl., App'x Ex. 1 ¶¶ 20-21 (Expert Report of James Morrison).

D. The FDA Approves Flonase

Flonase is a suspension-based steroid nasal spray. Suspension-based sprays contain undissolved solid particles that are dispersed throughout a liquid compound. Suspension-based sprays are distinct from solution-based sprays, where the solid is completely dissolved in a solvent.

In 1981, GSK filed a patent for Flonase in the United States. GSK subsequently filed an NDA, requesting FDA approval to market Flonase. In October 1994, the FDA approved Flonase to treat the nasal symptoms of seasonal allergic rhinitis, perennial allergic rhinitis, and perennial non-allergic rhinitis. Rhinitis is an inflammation of the nasal mucous membrane. Def. Mot. Summ. J. App'x A at 3 [hereinafter "GSK Glossary"]. Allergic rhinitis is a general term used to denote any allergic reaction of the nasal mucous membrane, and can occur seasonally (e.g., hay

[6] In 2007, Congress amended § 355 and explicitly allowed the FDA to approve an ANDA despite a pending citizen petition, unless the FDA determines that it is "necessary to protect the public health" to resolve the petition before approving an ANDA. See 21 U.S.C. § 355(q)(1)(A)(ii) (as amended); Food & Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (codified in various sections of titles 21, 42 of the U.S. Code). The 2007 Amendment also permitted the FDA to summarily deny citizen petitions "submitted with the primary purpose of delaying the approval of an application [where] the petition does not on its face raise valid scientific or regulatory issues . . . ." 21 U.S.C. § 355(q)(1)(E) (as amended). The 2007 Amendment occurred after GSK filed its citizen petitions and after the FDA approved Roxane's ANDA, and so does not govern the FDA's conduct in this case.

fever) or perennially. Id. at 1. Perennial rhinitis occurs continuously or intermittently throughout the year, while seasonal rhinitis occurs during specific times of the year. Id. at 3.

GSK released Flonase in the United States in 1995, and it quickly became the most prescribed suspension-based steroid nasal spray in the United States. By 2000, Flonase commanded 38% of brand-name steroid nasal spray sales nationally, resulting in over $600 million in sales. By 2005, the peak year for Flonase sales and the last full year of GSK's market exclusivity, Flonase sales exceeded $1.3 billion.

By May 2004, GSK had identified a number of generic pharmaceutical manufacturers, including Plaintiff Roxane Laboratories, Inc. ("Roxane"), that intended to file ANDAs for generic FP nasal sprays. This case concerns GSK's alleged "brand maturation strategy," crafted to maintain Flonase's market dominance in the face of inevitable generic competition. Plaintiffs argue that GSK's brand maturation strategy included filing several citizen petitions with the FDA, as well as a lawsuit in the District of Maryland, in order to restrain Flonase's generic competition.

E. Roxane Files First FP Nasal Spray ANDA in 2002

Until 1999, the FDA had not provided a framework for how an ANDA applicant might demonstrate BE compliance for nasal sprays such as Flonase that are intended for local action, rather than systematic absorption into the bloodstream. In 1999, the FDA solicited public comments on a draft guidance entitled Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (the "1999 Draft Guidance"). This guidance provided "recommendations to applicants who are planning product quality studies to measure bioavailability (BA) and/or establish bioequivalence (BE) in support

of new drug applications (NDAs) or abbreviated new drug applications (ANDAs) for locally acting drugs in nasal sprays . . . ." Def.'s Ex. 9 at 1 (1999 Draft Guidance).

Between August 2000 and November 2001, the FDA was still considering comments to the 1999 Draft Guidance, and so its position on how ANDA applicants could show BE compliance remained uncertain. During this period, Roxane met regularly with the FDA to discuss how Roxane could demonstrate BE compliance in its soon-to-be-filed ANDA. On October 3, 2002, after several such meetings, Roxane filed the first ANDA for a generic suspension-based FP nasal spray following the protocols outlined in the 1999 Draft Guidance and discussed with the FDA.

F. The FDA Issues its Second Nasal Spray Guidance in 2003

In April 2003, after considering comments on the 1999 Draft Guidance, the FDA issued a revised draft guidance entitled Draft Guidance for Industry: Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action (the "2003 Draft Guidance"). The 2003 Draft Guidance noted that it was not complete, and that a "series of attachments [were] being developed and [would] be posted with this draft guidance . . . ." Def.'s Ex. 10 at 3 (2003 Draft Guidance). The FDA did not issue a final guidance document.

G. GSK Files Citizen Petitions Commenting on the 2003 Draft Guidance, and the FDA Responds to those Petitions

1. GSK's May 19, 2004 Citizen Petition

On May 19, 2004, GSK submitted a citizen petition (the "May Petition") making five requests in response to the 2003 Draft Guidance. On February 22, 2006, the FDA responded to the May Petition and rejected each of GSK's five requests:

Request 1: That the FDA refrain from approving ANDAs prior to issuing final guidance and a statistical appendix

The May Petition requested that the FDA refrain from approving any ANDAs before issuing a finalized guidance. The FDA unequivocally rejected this request, stating:

> Neither the [Federal Food, Drug, and Cosmetic Act] nor FDA regulations require FDA to issue final guidance prior to approving an ANDA. As in the new drug approval process, FDA is required to make decisions based on the information provided by individual applicants and evaluate the scientific content of ANDAs to determine if the application meets the statutory and regulatory requirements (section 505(j) of the Act). GSK has cited no authority to support its position that the Agency must complete a guidance document prior to approving an ANDA for a fluticasone propionate nasal spray product. . . . Whether or not FDA issues final guidance does not speak to the scientific validity of FDA's bioequivalence methodology, scientific evaluation, and approval of generic fluticasone propionate nasal spray products.

Pls.' Ex. 8 at 21-22 (Feb. 22, 2006 FDA Letter Rejecting GSK's Citizen Petitions) [hereinafter "FDA Rejection Letter"].

Furthermore, the May Petition requested that the FDA refrain from approving any ANDAs prior to issuing an appendix of a priori statistical criteria with which to establish BE compliance (the "statistical appendix"). This statistical appendix would contain confidence intervals for statistical criteria relevant to BE compliance, serving as goalposts marking out an acceptable range of values for each relevant criterion. ANDA applicants would thus have a general idea of the range of data they would need to collect to demonstrate BE compliance.

FDA Response to Request #1:

The FDA conceded that it "is desirable" that final guidance be issued prior to ANDA approval but noted that "it is not always possible" to do so. The FDA also denied that it had to publish a statistical appendix before approving pending ANDAs. The FDA stated that in certain

situations, it simply lacks sufficient data to generate appropriate confidence intervals for different statistical criteria relevant to bioequivalence. Id. at 6. In such situations, the FDA considers the data that provided in the ANDA, and determines whether that data itself demonstrates BE compliance. Because it sometimes lacks the data with which to generate a priori confidence intervals, the FDA concluded that it was appropriate to consider pending ANDAs without a published statistical appendix.

Request #2: That the FDA require ANDAs to include data from PAR and PNAR studies

The FDA approved Flonase to treat the nasal symptoms of seasonal allergic rhinitis ("SAR"), perennial allergic rhinitis ("PAR"), and perennial non-allergic rhinitis ("PNAR"). The 2003 Draft Guidance provided that an ANDA could be approved to treat all three indications even if the application only included data from SAR patients. The May Petition urged the FDA to require ANDAs to include data from patients with all three indications.

FDA Response to Request #2:

The FDA rejected the request to require data from all three indications, stating that there is no reason to believe that drug performance would be any different in PNAR or PAR patients. The FDA noted that SAR-only studies are easier to conduct, and that absent any evidence that drug performance differs depending on the type of patient, it was unnecessary to require the extra expenditures needed to collect data from PNAR and PAR patients. Id. at 12.

Request #3: That the FDA require pharmacokinetic data to be collected over the entire dosage interval of in vivo tests

The FDA analyzes pharmacokinetic data generated from a single-dose treatment where the blood, plasma, or serum levels of a treated patient are measured over time. The 2003 Draft

Guidance required an applicant to take measurements at least four consecutive times during the dose interval. GSK requested that the FDA require ANDA applicants to collect data over the entire dosage interval. GSK argued that it is not possible to extrapolate data from any four measurements taken during a clinical test over the entire dosage interval.

FDA Response to Request #3:

The FDA declined GSK's request, stating that four consecutive samples are sufficient to determine whether two sprays provide the same exposure to the active ingredient. Id. at 13. The FDA declined to require more samples than it believed were necessary to show BE compliance.

Request #4: That the FDA reconsider its in vitro tests for plume geometry and container shelf life

The May Petition criticized the 2003 Draft Guidance's in vitro tests for plume geometry[7] and container shelf-life. Regarding plume geometry, the May Petition noted that the FDA requires ANDA applicants to measure the shape of the plume emitted in open air by a spray device. GSK argued that plume geometry in the open air is irrelevant because a spray device is used inside the nasal cavity in which a free plume cannot form. Regarding container shelf life, the May Petition urged the FDA to directly compare the shelf life of its products with actual units of the brand name equivalent.

FDA Response to Request #4:

The FDA rejected both of these criticisms. First, the FDA defended its plume geometry test, stating that plume geometry is a relevant criterion for nasal sprays. Although the FDA

[7] Plume geometry describes the cross-sectional shape of the spray emitted from the device, measured on a plane parallel to the direction of the spray, in other words, functioning as a "side view" of the spray cloud. Pls.' Ex. 22 ¶ 23 (Dalby Decl.).

conceded that the shape of the plume changes in the nasal cavity, the FDA stated that plume geometry directly bears on where in the nasal cavity the drug is ultimately deposited, and thus is relevant to spray performance. Id. at 16-17. Second, the FDA found that its container shelf life test was sufficient to establish an appropriate shelf life, and to ensure product equivalence over the entire shelf life of the product. Id.

Request #5: That the FDA reconsider its endorsement of the geometric mean ratio method

There are two statistical methods by which an ANDA applicant might show BE compliance: the population bioequivalence method, and the geometric mean ratio method. The population bioequivalence method considers both the average difference in therapeutic response to two compounds and the variability of the responses to each compound (variability measures the rate of deviation in the response to a single compound over a series of tests). The geometric mean ratio method, on the other hand, does not consider intra-product variability; that is, "two products could deliver the same dose on the average, but if one product delivered the intended dose consistently and the other product inconsistently" the products would be BE compliant using the population bioequivalence method, but would be BE compliant using the geometric mean ratio method. Pls. Ex. 108 at 12, 14 (Rodda Decl.). The 1999 Draft Guidance only endorsed the population bioequivalence method to show BE compliance. The 2003 Draft Guidance, however, endorsed the use of the geometric mean ratio method.

On June 16, 2005, GSK submitted a supplement to its May Petition (the "June Supplement").[8] This supplement raised concerns about the FDA's endorsement of the geometric mean ratio method in the 2003 Draft Guidance. The June Supplement argued that while the FDA's use of the geometric mean ratio methodology is appropriate for nasal solution products, the methodology is not appropriate for suspension-based nasal sprays. Def.'s Ex. 7 at 1 (June 16, 2005 GSK Supplement to May Petition).

FDA Response to Request #5:

The FDA rejected GSK's statistical criticisms of the geometric mean ratio methodology. Because the FDA ultimately endorsed only the Population Bioequivalence Method, the FDA found that GSK's criticisms were inapt and declined to address them directly. The FDA did note, however, that it "disagree[d] with [GSK's] arguments . . . ." FDA Rejection Letter at 11.

2. GSK's November 23, 2004 Citizen Petition

Request #6: That the FDA tighten specifications for DSD and SP

On November 23, 2004, GSK submitted a second citizen petition to the FDA (the "November Petition"). The November Petition addressed two criteria required in an ANDA's Chemistry and Manufacturing Controls ("CMC") section: (1) droplet size distribution ("DSD"), which measures the size of individual droplets emitted in a spray, and (2) spray pattern ("SP"), which describes the cross-sectional shape of the spray emitted by a device. Rather than an external comparison between the generic product and a reference product, CMC criteria such as DSD and SP provide an internal measure of the production quality of any given batch of a drug

[8] GSK submitted a prior supplement on January 6, 2005. That supplement is not relevant to this Motion.

product. When considering a pending ANDA, the FDA's chemistry division reviews submitted specifications for DSD and SP to ensure that the drug product will meet specified standards. DSD and SP are particularly important CMC criteria because they relate to the health implications of the delivery of droplets beyond the nose and into the lungs. GSK requested that the FDA require tighter specifications for DSD and SP, in order to ensure greater internal consistency within batches of generic nasal sprays.

FDA Response to Request #6

In its February 2006 letter rejecting the requests made in the May Petition, the FDA also rejected the requests that GSK made in the November Petition regarding DSD and SP. FDA Rejection Letter at 20. The FDA noted that "[e]ach firm develops its own proprietary product quality tests (e.g., to measure DSD and SP) that may use different equipment under different conditions. Because GSK's DSD and SP product quality tests and methodologies are proprietary, it is virtually impossible for a generic manufacturer to perform the exact same tests that GSK used for Flonase approval to compare test and reference products." Id. In other words, the exact DSD and SP specifications required of brand name and generic drugs will necessarily vary because the testing methodologies employed by each manufacturer are proprietary. As a result, the FDA declined to require generic manufacturers to adopt specifications comparable to those imposed on Flonase.

H. GSK Challenges the FDA's Approval of Plaintiff Roxane's ANDA in Court

On February 22, 2006, the same day that it denied GSK's citizen petitions, the FDA approved Roxane's ANDA. The next day, on February 23, 2006, GSK filed suit against the FDA in the United States District Court for the District of Maryland, requesting a temporary

restraining order against the approval of Roxane's ANDA because the approval was allegedly arbitrary and capricious, an abuse of discretion, and in violation of the law. Glaxo Grp. Ltd. v. Leavitt, No. 06-cv-469 (D. Md. filed Feb. 23, 2006), ECF No. 1. After holding a hearing regarding GSK's motion for a temporary restraining order, the court granted the Motion, noting that "GSK has demonstrated some likelihood of success on the merits." Order at 1, Glaxo Grp. Ltd. v. Leavitt, No. 06-cv-469 (D. Md. filed Feb. 24, 2006), ECF No. 6.

After the temporary restraining order was granted, the court considered the motion for a preliminary injunction. Motion, Glaxo Grp. Ltd. v. Leavitt, No. 06-cv-469 (D. Md. filed Mar. 1, 2006), ECF No. 21. After holding a hearing on the matter, Judge Andre M. Davis denied GSK's motion for a preliminary injunction. Order at 1, Glaxo Grp. Ltd. v. Leavitt, No. 06-cv-469 (D. Md. filed Mar. 7, 2006), ECF No. 39.

II. LEGAL STANDARD

Summary judgment will be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). There is a "genuine" issue of material fact if the evidence would permit a reasonable jury to find for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The "mere existence of a scintilla of evidence" is insufficient. Id. at 252.

The moving party must make an initial showing that there is no genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The non-movant must then "make a showing sufficient to establish the existence of [every] element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322; see also Fed. R. Civ. P. 56(c)(1). The non-moving party must "do more than simply show that there is some

metaphysical doubt as to the material facts." Matsushita Electric Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). In determining whether the non-moving party has established each element of its case, the court must draw all reasonable inferences in the non-moving party's favor. Id. at 587.

III. DISCUSSION

Plaintiffs have brought suit alleging that by filing citizen petitions with the FDA and by filing a lawsuit in the District of Maryland, GSK has violated state and federal antitrust laws. GSK now moves to dismiss Plaintiffs' Complaints, claiming that its conduct was immune from antitrust liability under the Noerr-Pennington doctrine. Because genuine issues of material fact remain as to whether GSK's conduct constituted "sham" petitioning that is not entitled to Noerr-Pennington immunity, I will deny GSK's Motion for Summary Judgment.

A. The "Sham" Exception to Noerr-Pennington Immunity

The First Amendment of the U.S. Constitution protects "the right of the people . . . to petition the Government for a redress of grievances." U.S. Const. amend. I. A party that exercises its First Amendment right to "petition[ ] the government for redress generally is immune from antitrust liability." Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 122 (3d Cir. 1999) (citing E. R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965)).[9] This doctrine, known as the Noerr-Pennington doctrine, "governs the approach of citizens or groups of them to

[9] Because this immunity derives from the First Amendment, it also applies to antitrust liability arising out of state law. Cheminor, 168 F.3d at 128. As a result, the analysis is the same for the Indirect Purchasers case as for the other two cases.

administrative agencies (which are both creatures of the legislature, and arms of the executive) and to the courts . . . ." Calif. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972). The Supreme Court has also stated, in what has since become known as the "sham" exception to the Noerr-Pennington doctrine, that a party is not entitled to immunity where the activity "ostensibly directed toward influencing governmental action [ ] is a mere sham to cover . . . an attempt to interfere directly with the business relationships of a competitor . . . ." Noerr, 365 U.S. at 144.

In Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc. [hereinafter PRE], 508 U.S. 49 (1993), the Supreme Court set out a two-pronged test to determine whether a party's conduct is a sham therefore not entitled to Noerr-Pennington immunity.[10] Although PRE only discussed the sham exception in the context of litigation, the

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[10] Circuit courts have created two alternative tests to determine whether specific subsets of petitioners are exempt from Noerr-Pennington immunity for filing sham petitions. First, the Third Circuit has created a test for the subset of petitioners who misrepresented facts at the core of their petition. Cheminor, 168 F.3d at 122-23; see also Armstrong Surgical Ctr., Inc. v. Armstrong Cnty. Mem'l Hosp., 185 F.3d 154, 158 n.2 (3d Cir. 1999). Plaintiffs request that GSK's petitions be considered under the Cheminor test because they certified that their petitions contained all information unfavorable to their petitions, while failing to include in their petitions the fact that GSK employees personally believed that their petitions did not implicate any safety or efficacy concerns. GSK's certification, however, is not a "fact" within the meaning of Cheminor, and certainly does not go to the heart of GSK's petitions. Plaintiffs' request thus fails.

Second, the Ninth Circuit has set out a test for the subset of cases where the petitioner has engaged in a pattern or practice of filing successive petitions that has since been adopted by the Second Circuit and the Federal Circuit. USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL-CIO, 31 F.3d 800, 810-11 (9th Cir. 1994); ERBE Elektromedizin GmbH v. Canady Tech. LLC, 629 F.3d 1278, 1291 (Fed. Cir. 2010); Primetime 24 Joint Venture v. Nat'l Broad. Co., 219 F.3d 92, 101 (2d Cir. 2000). In order to qualify as a "pattern or practice" of successive filings, however, the number of petitions must be voluminous. Here, GSK's conduct consists of, at most, five "petitions": (1) the May Petition; (2) the June Supplement; (3) the November Petition; (4) the Petition for Stay; and (5) filing a lawsuit in the

test also generally applies to petitions to administrative agencies.[11] Cheminor, 168 F.3d at 123 (applying the PRE test to petitions to the International Trade Commission and the Department of Commerce); In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009) (applying the PRE test to a citizen petition filed with the FDA).

The question whether a petition is a sham "is generally a question of fact for the jury[.]" Indep. Taxicab Drivers' Emps. v. Greater Hous. Transp. Co., 760 F.2d 607, 612 n.9 (5th Cir. 1985); see also Catch Curve, Inc. v. Venali, Inc., 519 F. Supp. 2d 1028, 1037 (C.D. Cal. 2007)

District of Maryland to contest the approval of Roxane's ANDA. No court has applied the USS-POSCO test to a "series" of five petitions; indeed, courts have expressly declined to apply the test in cases involving up to nine petitions. See Livingston Downs Racing Ass'n v. Jefferson Downs Corp., 192 F. Supp. 2d 519, 538-39 (M.D. La. 2001) (declining to apply the USS-POSCO test to a series of nine petitions); see also ERBE, 629 F.3d at 1291 (declining to apply the USS-POSCO test to a series of three lawsuits); Amarel v. Connell, 102 F.3d 1494, 1519-20 (9th Cir. 1996) (declining to apply the USS-POSCO test to a series of two lawsuits). Because GSK's conduct does not fit within the subset of activity that could be considered under either the USS-POSCO or Cheminor tests, its conduct must be considered under the general PRE test.

[11] GSK points to a Ninth Circuit decision from 1998 that supposedly distinguishes between agencies acting in "adjudicatory" capacities with agencies acting in"non-adjudicatory" capacities, only applying the PRE test to petitions to agencies acting in an "adjudicatory" capacity. See Kottle v. Nw. Kidney Ctrs., 146 F.3d 1056, 1060 (9th Cir. 1998). Even if Kottle did create such a distinction, the Third Circuit and courts within this Circuit have consistently and without reservation applied the objective prong to comparable administrative agency petitions. See, e.g., Cheminor, 168 F.3d at 123 n.10 (applying the objective prong to petitions to the International Trade Commission and the Department of Commerce); Borough of Lansdale v. PP & L, Inc., 426 F. Supp. 2d 264, 280 (E.D. Pa. 2006) (applying the objective prong to petitions to various Pennsylvania administrative agencies); PennPac Int'l, Inc. v. Rotonics Mfg., Inc., No. 99-2890, 2001 WL 569264, at *7 (E.D. Pa. May 25, 2001) (applying the objective prong to petitions to the Patent and Trademark Office). Moreover, every court that has considered whether a petition to the FDA is entitled to Noerr-Pennington immunity has applied the PRE test. See, e.g., In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 694 (2d Cir. 2009) (applying the PRE test to a citizen petition filed with the FDA); AstraZeneca AB v. Mylan Labs. Inc., No. 00-cv-6749, 2010 WL 2079722, at *3 (S.D.N.Y. May 19, 2010) (same); La. Wholesale Drug Co. v. Sanofi-Aventis, No. 07-cv-7347, 2009 WL 2708110, at *5-7 (S.D.N.Y. Aug. 28, 2009) (same).

("[W]hether something is a genuine effort to influence governmental action, or a mere sham, is a question of fact." (quoting Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc., 690 F.2d 1240, 1253 (9th Cir. 1982))); Kravco Co. v. Valley Forge Ctr. Assocs., No. 91-cv-4932, 1992 WL 97926, at *3 (E.D. Pa. Apr. 30, 1992) ("Whether or not the acts of the defendants fit the sham exception is a factual issue . . . ."). A court should only rule on the objective baselessness prong as a matter of law "[w]here there is no dispute over the predicate facts of the underlying [petitions]." PRE, 508 U.S. at 60-61.

Under PRE, the burden falls on the party invoking the sham exception, here the Plaintiffs, to show that the conduct at issue constitutes a sham.[12] IGEN Int'l, Inc. v. Roche Diagnostics GmbH, 335 F.3d 303, 312 (4th Cir. 2003); USS-POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL-CIO, 31 F.3d 800, 811 (9th Cir. 1994). First, Plaintiffs must show that the petition was "objectively baseless in the sense that no reasonable [party] could realistically expect success on the merits. If an objective [party] could conclude that the [petition] is reasonably calculated to elicit a favorable outcome, the [petition] is immunized under Noerr, and an antitrust claim premised on the sham exception must fail." PRE, 508 U.S. at 60. This is known as the objective prong of the PRE test. The objective prong requires Plaintiffs to show that a reasonable petitioner could not realistically expect that the petition will succeed on its merits. See Cheminor, 168 F.3d at 122-23 (discussing whether a petitioner could "realistically

[12] The parties dispute whether Plaintiffs must prove objective baselessness using a preponderance of the evidence standard, or the stricter clear and convincing evidence standard. Although district courts in this Circuit have opined on the issue, the Third Circuit has yet to state what the proper standard is in the context of a sham petition claim. I need not consider the distinction between the two standards here, where Plaintiffs' evidence, construed in the light most favorable to them, is sufficient to survive summary judgment under either standard.

expect" to succeed on the merits); see also Bryant v. Military Dep't of Miss., 597 F.3d 678, 693 (5th Cir. 2010) (same). Courts have sometimes referred to a showing of a realistic expectation of success on the merits as a showing of "probable cause." See, e.g., PRE, 508 U.S. at 54. Both characterizations of the objective prong, however, ultimately raise the same question—whether any "reasonable litigant could realistically expect success on the merits" of the petition. See generally Cheminor, 168 F.3d at 122-23; Bryant, 597 F.3d at 691; Nader v. Democratic Nat'l Comm., 567 F.3d 692, 699 (D.C. Cir. 2009); Theme Promotions, Inc. v. News Am. Mktg. FSI, 546 F.3d 991, 1007 (9th Cir. 2008); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213 (2d Cir. 2006).

"Only if challenged [conduct] is objectively meritless may a court examine the litigant's subjective motivation" to determine if the conduct "conceals 'an attempt to interfere directly with the business . . . of a competitor.'" PRE, 508 U.S. at 60-61 (quoting Noerr, 365 U.S. at 144). This second prong is known as the subjective prong. If Plaintiffs can show that the petitions were objectively baseless, Plaintiffs must then show that the subjective intent of the petitioning party was to inhibit competition, rather than to petition the Government for redress. PRE, 508 U.S. at 60-61. GSK concedes for purposes of this Motion that Plaintiffs have provided sufficient evidence to survive summary judgment on the second prong. The only issue before me is thus whether Plaintiffs have carried their burden in showing that GSK's conduct was objectively baseless.

B. GSK's Conduct Under The PRE Test

In order to show that GSK's conduct was objectively baseless, Plaintiffs must be able to show that a reasonable petitioner would realistically expect GSK's citizen petitions or GSK's

lawsuit to succeed on their merits.[13] Plaintiffs do not need to show a realistic expectation of success on all of GSK's arguments in each petition and its lawsuit. Rather, conduct is not a sham if "at least one claim in the [petition] has objective merit." Dentsply Int'l, Inc. v. New Tech. Co., No. 96-cv-272, 1996 WL 756766, at *2 (D. Del. Dec. 19, 1996).[14]

1. The May Petition

GSK made five requests in the May Petition and the June Supplement. If Plaintiffs cannot show that all of these requests were objectively baseless, they fail to carry their burden under PRE, and the May Petition will be protected by Noerr-Pennington immunity. Dentsply, 1996 WL 756766, at *2.

Request 1: That the FDA refrain from approving ANDAs prior to issuing final guidance and a statistical appendix

Genuine issues of fact remain as to the objective basis for GSK's request that the FDA refrain from approving any pending ANDAs before finalizing the 2003 Draft Guidance. As Plaintiffs note, the FDA was not obligated to issue any guidance, let alone a final guidance. Even if the FDA released a final guidance, ANDA applicants would not be obligated to use the methods described in the guidance. See 21 U.S.C. § 355(i)(8)(A)-(B). Indeed, guidances are specifically prohibited from including "mandatory language such as 'shall,' 'must,' 'required' or

[13] GSK also argues in a single page in its Reply Brief that its communications with United States Pharmacopeia ("USP") are protected by Noerr-Pennington. Neither party has adequately briefed this issue, and I decline to opine on this issue when it has not been sufficiently developed.

[14] The May Petition and the June Supplement must be considered together because GSK intended that the FDA consider the two documents jointly, thus the two documents together comprise a single instance of petitioning the FDA. See generally PRE, 508 U.S. at 60 (considering a lawsuit as one collective act of petitioning, as opposed to considering each filing independently); In re DDAVP, 585 F.3d at 686.

'requirement,'" unless describing an independent statutory requirement, and instead serve only as advisory documents. 21 C.F.R. § 10.115(i)(2). As a result, it is an open question whether there was any need to issue final guidance before approving an ANDA, and thus whether there was a realistic chance that this request would succeed on its merits.

Plaintiffs also present expert testimony stating that the FDA regularly approved nasal spray products without a finalized FDA guidance, and that the 2003 Draft Guidance provided "more than enough information to potential generic manufacturers . . . to establish BE for a nasal spray product." Dalby Decl. ¶¶ 40-44. In fact, Plaintiffs' expert testified that refraining from approving an ANDA before issuing final guidance would be contrary to FDA practice. Id. Plaintiffs also provide testimony from Robert Pollock ("Pollock"), the former Acting Director of the FDA's Office of Generic Drugs, who expressed skepticism that such an argument would ever be adopted by the FDA, stating that "[i]f we had to wait for the FDA to finalize a guidance before a drug was approved, we would never get any approvals." Pls.' Ex. 33 (Pollock Dep. 148:7-10, July 30, 2010). Indeed, GSK employees even stated that GSK "[didn't] think approval of generic Flonase requires the [FDA] guidance to be finalized." Pls.' Ex. 47 (E-mail from Roger Gaby to Jim Russell (July 19, 2004)). GSK's own experts conceded the same. See Pls.' Ex. 32 (Pendergast Dep. 99:23-25, Sept. 22, 2010); Pls.' Ex. 29 (Hochhaus Dep. 100:21-23, 110:16, Sept. 10, 2010).

Genuine issues of fact also remain as to the objective basis for GSK's request that the FDA refrain from approving any pending ANDAs before producing a statistical appendix. As Plaintiffs' expert notes, producing such an appendix is often impossible prior to ANDA approval because the FDA often lacks the clinical data with which to generate appropriate confidence

intervals. Dalby Decl. ¶¶ 45-50. Plaintiffs also provide evidence relating to GSK's experience with Ventolin, another brand-name drug that it manufactured, that shows that GSK was well aware "that the FDA had a history of approving locally acting, suspension-type generic products in the absence of a priori establishment of statistical criteria." Id. ¶ 49. Plaintiffs' evidence is sufficient to raise genuine issues of material fact as to the objective basis for GSK's request that the FDA refrain from approving ANDAs absent final guidance and a statistical appendix.

Request #2: That the FDA require ANDAs to include data from PAR and PNAR studies

Genuine issues of fact also remain as to the objective basis for GSK's request that the FDA require ANDAs to include data from PNAR and PAR tests. First, as Plaintiffs note, FDA Guidances cannot require ANDA applicants to perform specific tests unless those tests are required by statute or regulation. 21 C.F.R. § 10.115(i)(2) ("[FDA] Guidance documents must not include mandatory language . . . unless FDA is using these words to describe a statutory or regulatory requirement."). The parties have not identified any statutory or regulatory requirement that ANDA applicants perform tests on all three indications, so it is an open question whether the FDA was able to require ANDA applicants to perform PNAR and PAR tests at all.

Alternatively, Plaintiffs provide expert testimony that PNAR and PAR data would be redundant.[15] See Dalby Decl. ¶¶ 51-56 ("If the [brand name] product is effective for SAR and the

[15] Of course in considering the FDA's rejection of GSK's proposals, I must be careful to "resist the understandable temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." PRE, 508 U.S. at 60 n.5. The fact that the FDA rejected GSK's petitions does not mean that GSK's requests were objectively baseless. The substantive reasons that the FDA offered to justify rejecting the requests, however, bear on the objective baselessness of each request.

[generic] product is shown to be equivalent to the [brand name] product in treating SAR . . . the FDA concludes that the [generic] product would be as effective as the [brand name] product for treating all indications claimed by the [brand name] product."). Plaintiffs also point to the FDA's letter rejecting GSK's petitions, which reached the same conclusion. FDA Rejection Letter at 11-13 ("Because the goal of bioequivalence studies is to test the equivalence of in vivo formulation performance, it is redundant to test each indication separately."). Plaintiffs' evidence is sufficient to raise a genuine issue of fact as to whether PNAR and PAR data would have been redundant, and thus whether this request was objectively baseless.

Request #3: That the FDA require pharmacokinetic data to be collected over the entire dosage interval of in vivo tests

Genuine issues of fact also remain as to the objective basis for GSK's request that ANDA applicants collect pharmacokinetic data over the entire dosage interval of their in vivo tests, rather than collecting four sample measurements and extrapolating the measurements over the rest of the dosage interval. As the FDA recognized, it is certainly preferable to collect data over the entire dosage interval where possible. GSK does not, however, simply argue in favor collecting data over the entire dosage interval; rather, GSK argues that the FDA's current standard of four consecutive measurements is not sufficient to ensure BE compliance. To show that this request was a sham, Plaintiffs point to the FDA's letter rejecting GSK's petitions, which concluded that four consecutive samples during the dosage interval is sufficient to establish BE compliance. FDA Rejection Letter at 13-14 ("FDA believes that four consecutive sampling times using the maximum clinical dose is sufficient to detect whether two [FP] nasal spray suspension products [are bioequivalent]."). Plaintiffs also present expert testimony that GSK's

proposed alternative "requires a level of drug specific detail that is not desirable in a Guidance . . . [because Guidances] are usually directed at . . . methods applicable to many products." See Dalby Decl. ¶¶ 57-64. Plaintiffs' evidence is sufficient to raise a genuine issue of fact as to whether there was a realistic chance that the FDA would require ANDA applicants to provide more data than was necessary.

Request #4: That the FDA reconsider its in vitro tests for plume geometry and container shelf life

Genuine issues of fact also remain as to the objective basis for GSK's criticisms of the FDA's method for in vitro testing of plume geometry and container shelf life. First, Plaintiffs concede that the plume geometry of a spray is different when the spray is released in the nasal cavity. Plaintiffs present expert testimony, however, that plume geometry is a relevant criterion for ANDA applicants because it directly bears on where the drug is deposited inside the nasal cavity. Dalby Decl. ¶ 65 (concluding that the FDA's open air testing method for plume geometry was more discriminating than a test in a constricted space like the nasal cavity). Plaintiffs additionally point to the FDA's letter rejecting GSK's petitions, which also found that plume geometry relates to "where in the nasal cavity [the] drug is deposited. FDA Rejection Letter at 18. The objective basis for GSK's criticism of the plume geometry test is thus an open question of fact.

Second, Plaintiffs present expert testimony that GSK's proposed alternative method to test container shelf life was impossible, because generic manufacturers cannot accurately determine the shelf life of a reference product and because generic manufacturers may not be able to purchase reference products new enough to survive the proposed study. Dalby Decl. ¶ 65

(concluding that "a head-to-head comparison over the entire shelf-life of the products . . . is impossible"). Additionally, Plaintiffs point to the FDA's letter stating that its method for testing container shelf life was sufficient "to ensure that generic versions of the [FP] nasal spray product preserve identity, strength, quality, and purity over their shelf life." FDA Rejection Letter at 17. Plaintiffs' evidence is sufficient to raise genuine issues of fact as to whether GSK's proposed alternative test for container shelf life was possible, and thus whether the request had an objective basis.

Request #5: That the FDA reconsider its endorsement of the geometric mean ratio method

Finally, genuine issues of fact remain as to the objective basis for GSK's statistical criticisms of the geometric mean ratio method. Plaintiffs present expert testimony that GSK's criticisms were irrelevant to Flonase, because the criticisms were supported exclusively by analysis of clinical data from a solution-based nasal spray. Flonase is a suspension-based spray, and suspension-based sprays are influenced by a range of variables, such as drug particle aggregation and sedimentation, that may not be relevant for solution-based sprays. Dalby Decl. ¶¶ 87-90 (discussing why data from solution-based sprays may not be relevant to suspension-based sprays). It thus remains an open question whether GSK's criticisms were at all relevant to Flonase.

GSK's argues that FDA's ultimate endorsement of the population bioequivalence method over the geometric mean ratio method implies that GSK's criticisms of the geometric mean ratio methodology succeeded on the merits. GSK has not, however, presented any evidence that the FDA's decision to endorse the population bioequivalence method was motivated by GSK's

criticisms.[16] In fact, the FDA specifically stated in its response letter that GSK's criticisms were not relevant to Flonase, and that it disagreed with them. FDA Rejection Letter at 10-11 ("GSK's arguments against use of the geometric mean ratio method are not relevant . . . ; therefore, although we disagree with these arguments, we will not respond to them in this response."). Absent evidence connecting the FDA's change in position to GSK's criticisms, the FDA's action are minimally probative, if probative at all, of the substantive merits of GSK's criticisms. Thus a genuine issue of fact remains as to the objective basis for GSK's criticism of the geometric mean ratio method.

2. The November Petition

Request #6: That the FDA tighten specifications for DSD and SP

GSK's November Petition requested that the FDA tighten the DSD and SP specifications for generic manufacturers to reflect the same standards imposed on Flonase in its post-marketing supplements. GSK claimed that this request was motivated by its own experience with the FDA. From 1997 to 2004, the FDA continually required GSK to adopt certain "post-marketing" supplements to its DSD and SP specifications.[17] GSK argues that the November Petition merely

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[16] At the April 21, 2011 oral argument on this Motion, GSK argued that a citizen petition to the FDA succeeds on the merits if it influences an ongoing debate. As a result, GSK argues that GSK's petitions had an objective basis because they contributed to an ongoing scientific debate regarding BE compliance for solution-based nasal sprays. The fact that GSK simply "contributed to the debate" is not enough to entitle GSK's petitions to Noerr-Pennington immunity. If that were the standard, essentially any petition with any arguable scientific basis would survive the objective prong. PRE made clear that the objective prong requires more—Specifically, the arguments advanced by GSK must have had a realistic chance of "elicit[ing] a favorable outcome." PRE, 508 U.S. at 60.

[17] A post-marketing supplement is one that is adopted after an NDA or ANDA has already been approved by the FDA. The manufacturer is generally allowed to continue to market the product

requested that the FDA refrain from approving any ANDA unless the product met DSD and SP standards comparable to those that were imposed on Flonase.

Plaintiffs present evidence that the FDA could not require the same specifications because the testing methods employed to measure specifications like DSD and SP are proprietary—Plaintiffs argue that because these methods are proprietary, the specifications for different products will necessarily be different. See Dalby Decl. ¶¶ 66-71 ("Generic companies may not evaluate the [generic] and [brand name] product[s] in exactly the same way, or use the same instruments as the innovator (and they cannot because the innovator's test methods are proprietary)."); see also 21 C.F.R. § 314.50(d)(1)(ii)(A) (recognizing the proprietary nature of DSD and SP specifications by requiring that each ANDA applicant provide its own distinct specifications).

GSK argues that it only requested comparable SP and DSD specifications, not that the specifications be identical. This distinction is irrelevant—in order to determine whether specifications are comparable, generic manufacturers would still need access to GSK's proprietary specifications. Moreover, even if the distinction were relevant, Plaintiffs dispute this characterization of the November Petition, rendering the precise meaning of GSK's request a disputed question of fact.

Plaintiffs' also present expert testimony that the FDA's existing DSD and SP standards were sufficient to ensure public safety. With no public safety implications, it an open question whether GSK could realistically expect the FDA to hold up the ANDA application process

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while it works to address the problem identified by the FDA.

before tightening DSD and SP specifications. Dalby Decl. ¶¶ 72-86. As Plaintiffs' expert notes, to the extent that there were any concerns with generic DSD and SP standards, the FDA could have addressed those concerns through post-marketing supplements, as it did with Flonase. Indeed, Flonase's own DSD and SP specifications were tightened through post-marketing supplements after GSK's NDA was approved—a fact that GSK explicitly recognized at a September 2002 strategy meeting. Pls.' Ex. 105 at 7 (Notes, Sept. 24, 2002, Flonase Fragrance Free Strategy Meeting) ("Given that the FDA has worked with us for 3 years to address SP & DSD, it is likely that the [FDA] will give a generic company some leeway in addressing any similar criteria issues.").

GSK points to an internal Roxane e-mail stating that "[t]he arguments presented by Glaxo [in the November Petition] are strong and scientifically based. They quote the FDCA act, CFR, draft guidance documents for CMC requirements for nasal products, and court cases." Def.'s Ex. 37 at 2 (Elizabeth Ernst e-mail to Thomas Murphy, et al. (Dec. 6, 2004)). Whether or not GSK's arguments were "strong and scientifically based" is still in dispute—while Ersnt may have believed the petition had an objective basis, Plaintiffs' experts argue to the contrary. Moreover, Ernst's statement at most constitutes evidence that Roxane believed that the November Petition raised strong arguments. Here, however, the question is whether a reasonable petitioner would have realistically expected the petition to succeed on the merits.

Ernst's e-mail does not establish that the November Petition had an objective basis as a matter of law, and does not undermine Plaintiffs' argument that the requests made in the November Petition would have been dealt with in a post-marketing supplement, and thus could not have succeeded. Plaintiffs' evidence is sufficient to raise genuine issues of fact as to whether

the November Petition requested relief that was contrary to FDA practice, and thus whether the November Petition was objectively baseless.

3. The Maryland Lawsuit

Although they did not raise the issue in their Opening Brief, GSK argues in its Reply Brief that its lawsuit in the District of Maryland, filed after the FDA denied its citizen petitions and approved Roxane's ANDA, is entitled to Noerr-Pennington immunity. Glaxo Grp. Ltd. v. Leavitt, No. 06-cv-649 (D. Md. Feb. 23, 2006). GSK argues that the fact that Judge Richard Bennett granted GSK a temporary restraining order ("TRO") against the FDA necessarily shows that this lawsuit had an objective basis. This argument confuses the requirements for a TRO with the requirements to prove sham petitioning under PRE. Judge Bennett found that there was some likelihood that GSK's lawsuit would succeed on the merits—a requirement in order to obtain a TRO against the FDA. See id., ECF No. 6. Judge Bennett did not find that GSK would likely succeed on the merits, or even that there was a realistic chance of success on the merits. Judge Bennett's TRO thus does not necessarily establish that GSK's lawsuit had an objective basis.

Judge Bennett's determination may be probative of whether or not the Maryland lawsuit was objectively baseless; it does not, however, establish an objective basis as a matter of law. See FilmTec Corp. v. Hydranautics, 67 F.3d 931, 938 (Fed. Cir. 1995) (stating that even a successful preliminary injunction "does not necessarily preclude a court from concluding that litigation was baseless"). Cf. In re Relafen Antitrust Litig., 360 F. Supp. 2d 166, 176 (D. Mass. 2005) (stating that an alleged sham lawsuit may be objectively baseless even if the underlying lawsuit survived summary judgment because factors other than the substantive merits in the litigation may have allowed the lawsuit to survive). Indeed, when Judge Davis reconsidered the

issue in conjunction with GSK's Motion for a Preliminary Injunction, he denied the Motion in no uncertain terms, stating:

> If I had any hesitation, and a man without hesitation is a dangerous man, I understand that. But if I had any hesitation whatsoever that you had any kind of likelihood of prevailing in this case, I would not hesitate. But I simply don't have it. . . . I just don't see any likelihood that you're going to prevail.

Pls.' Ex. 14 (Prelim. Inj. Hr'g 124:4-17, Mar. 6, 2006). Judge Davis' strong denial of a preliminary injunction, along with Plaintiffs' evidence of the objective baselessness of the substantive requests made in GSK's citizen petitions, are sufficient to raise genuine issues of fact as to whether the Maryland lawsuit was objectively baseless.

V. CONCLUSION

Because genuine issues of fact remain as to whether GSK's conduct was objectively baseless, and thus constitutes "sham" petitioning not entitled to Noerr-Pennington immunity, I will **DENY** GSK's Motion for Summary Judgment on Noerr-Pennington grounds.

s/Anita B. Brody

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ANITA B. BRODY, J.

Copies **VIA ECF** on _____ to:

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